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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,277	03/09/2006	Hideyuki Okano	09707.0009	6053

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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08/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/571,277

Applicant(s)

OKANO ET AL.

Examiner

Maria Leavitt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1, 2, 5-7 and 27 drawn to a method for enhancing proliferation of a neural stem cell in liquid medium and neurite extension comprising overexpressing **Galectin-1** or **Galectin-3** in neuronal stem cells.
- II. Claims 3, 4, 5-7 and 27 drawn to a method for enhancing proliferation of a neural stem cell in liquid medium comprising culturing the stem cells in a medium comprising **Galectin-1** or **Galectin-3**.
- III. Claims 8-11 and 28 drawn to a pharmaceutical composition comprising in neuronal stem cells wherein **Galectin-1** or **Galectin-3** or a **C-S mutant Galectin-1** is overexpressed.
- IV. Claims 12, 13, 15, 16, 27 and 29 drawn to a therapy method for cerebral ischemia comprising transplanting neuronal stem cells wherein **Galectin-1** or **Galectin-3** or a **C-S mutant Galectin-1** is overexpressed
- V. Claims 14, 17, 20, and 30 drawn to an enhancer for neurite extension comprising **Galectin-1** or **Galectin-3** or a **C-S mutant Galectin-1** as an active ingredient.
- VI. Claims 18, 19, 21, 22 and 27 drawn to a method for enhancing *in vivo* proliferation of a neuronal stem cell or a n SVZ astrocyte wherein **Galectin-1** or **Galectin-3** is injected into the brain.

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- VII. Claims 23, 25 and 26 drawn to a method for assaying a target substance added into a liquid for enhancing proliferation of stem cells comprising **seeding a neuronal stem cell** into said medium to observe proliferation in relation to a control medium.
- VIII. Claims 24, 25 and 26 drawn to a method for assaying a target substance added into a liquid for enhancing proliferation of stem cells comprising **selecting a CD15+ neuronal stem cell** and **seeding a CD15+ neuronal stem cell** into said medium to observe proliferation in relation to a control medium.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

“If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present”

37 CFR 1.475 (d) also states:

“If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)”.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-VIII appears to be that they all relate methods and compositions for inducing proliferation and/or survival of neuronal stem cells by

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overexpressing Galectin-1 or -3 in the neuronal cell or by adding Galectin-1 or -3 to the culture medium. However, prior art has taught in vitro proliferation of neuronal stem cells in response to non-CNS mitogen factors such as FGF-2 and EGF, thrombopoietin and stem cell factor in the presence of retinoic acid Minger et.al., 2001, Center for Neuroscience Research, London, United Kingdom, Abstract). Therefore, the technical feature linking the invention of groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

A method for enhancing proliferation of a neuronal stem cell and neuronal extension comprising overexpressing Galectin-1 or -3 in said neuronal cells as claimed in Group I is functionally different from the method claimed in Group II wherein the method for enhancing proliferation of a neuronal stem cell and neuronal extension does not required transfection of a neuronal cell with a vector encoding the Galectin-1 or -3 genes for expression of said protein. Hence invention of Group I and Group II are drawn to methodologies with different modes of operation, each being used in different capacities, having different functions and producing different effects. Similarly, the inventions of Group III drawn to a pharmaceutical composition comprising neuronal stem cells wherein Galectin-1 or -3 is overexpressed in said neuronal cells is different from the enhancer comprising Galectin-1 or -3 as the active ingredient as claimed in Group V, because the active ingredient does not required to be expressed in a neuronal stem cell and can be prepared by chemical synthesis. Moreover, the invention of Group VIII, drawn to a

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method for assaying a target substance for enhancing stem cell proliferation requires the step of selecting a CD15+ neuronal stem cell population which step is not claimed or required by the method claimed in Group VII. Thus The methodology of Group VII is not coextensive to the methodology of Group VIII. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should Groups **I, II, II, IV, V, VI, VII or VIII** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A Galectin molecule as recited in claims 1, 2, 3, 4, 8, 9, 12, 13, 14-22, 27-30, selected from one of the following molecules:

- i) **Galectin-1** or a,
- ii) **Galectin-3**, and
- iii) **C-S mutant Galectin-1**,

The species are independent or distinct because there are methods comprising **lectin molecules** having different chemical structures, physical properties, and biological functions as a result of containing expressed genes. For example, antibodies raised against Galectin-1 would not necessary neutralize Galectin-3 as these two molecules comprise different immunogenic epitopes. Thus, the combined features of a particular species, distinct structurally and

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functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 3, 8, 12, 14, 18, and 24 are generic.

Should **Group I or II** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

2) A specifically named conditioned medium as recited in **claims 5, 6 and 7**, selected from one of the following:

- i) a neural stem cell conditioned medium,
- ii) a neurosphere conditioned medium, and
- iii) an OP cell line conditioned medium.

The species are independent or distinct because there are methods comprising conditioned medium with molecules having different chemical structures, physical properties, and biological functions as a result of containing different chemical compounds. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 3, 8, 12, 14, 18, and 24 are generic.

Should **Group III** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

3) A specifically named higher cerebral function as recited in **claims 10 and 11**, selected from one of the following:

- i) a motor function, and
- ii) a sensory function.

The species are independent or distinct because there are higher cerebral functions damaged by ischemia having different physical properties and biological functions as a result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 3, 8, 12, 14, 18, and 24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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/Joseph Woitach/

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